K030627

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Bard Electrophysiology
C.R. Bard, Inc.
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OCT 2 3 2003

BARD

VI. 510(k) SUMMARY FOR THE ORBITER PV DIAGNOSTIC ELECTRODE CATHETER

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

A. Submitter's Information

Name:	C.R. Bard, Inc.
Address:	55 Technology Drive, Suite 1 Lowell, MA 01851
Phone:	(978) 323-2216 (Direct Line)
Fax:	(978) 323-2222
Contact Person:	Deborah L. Herrington Regulatory Affairs Manager
Date of Preparation:	February 26, 2003

B. Device Name:

Trade Name:	Orbiter PV Diagnostic Electrode Catheter
Common/Usual Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter

C. Predicate Device Name(s):

Orbiter ST Diagnostic Electrode Catheter
Viking Diagnostic Electrode Catheter
Bard Woven Electrode Catheter

D. Device Description/Indications for Use:

Description

The Orbiter PV Diagnostic Electrode Catheter is a closed lumen, steerable device. Typical of electrode recording catheters currently sold, the Orbiter PV catheter will be offered in 7.5F diameter (7F shaft with a 5F tip) with 1-24 electrodes with a variety of inter-electrode spacings. The distal curve is capable of forming a 360-degree loop.

Indications:

Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

E. Technological Characteristics/Performance Data Summary

K992372

The predicate device for this 510(k) Premarket Notification is the currently marketed Bard Orbiter ST Diagnostic Electrode catheter. Where appropriate, other Bard devices are referenced as supplemental predicate devices including the Viking catheter (K971265/FDA concurrence October 23, 1997) and the Woven catheter (Preamendment device).

Refer to Appendix 4 for the Instructions for Use for the predicate device and the supplemental predicate devices.

Appendix 5 contains the information demonstrating Preamendment Status for the Bard Woven Electrode Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Bard Electrophysiology
c/o Ms. Deborah L. Herrington
Manager, Regulatory Affairs
C.R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851

Re: K030627
Trade Name: Orbiter PV Diagnostic Electrode Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: September 18, 2003
Received: September 22, 2003

Dear Ms. Herrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE

Diagnostic Electrode Catheter

Device Name: Orbiter PV Diagnostic Electrode Catheter
The Orbiter PV catheter will initially be offered in both the 14-pole and 24-pole design.

Indications for Use: Bard Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Contraindications: The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. Intracardiac mural thrombus).

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

The retrograde transaortic approach is contraindicated due to the risk of entrapping the tip in the left ventricle.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030627

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)